

CLAIMS

1. A soft gelatin capsule containing a pharmaceutical formulation comprising at least one omega-3 polyunsaturated fatty acid in free acid form or a pharmacologically acceptable derivative thereof characterised in that the capsule comprises gelatin extracted by an extraction process comprising acid pre-treatment of a collagen source.
2. A soft gelatin capsule as claimed in Claim 1 wherein formulation comprises 5, 8, 11, 14, 17-eicosapentaenoic acid (or "EPA").
3. A soft gelatin capsule as claimed in Claim 2 wherein EPA is present in an amount of at least about 50 wt % of the formulation.
4. A soft gelatin capsule as claimed in Claim 2 or Claim 3 wherein EPA is present in an amount of between from about 50 wt % to about 60 wt % of the formulation.
5. A soft gelatin capsule as claimed in Claim 2 or Claim 3 wherein EPA is present in an amount of at least about 90 wt % of the formulation.
6. A soft gelatin capsule as claimed in any of the preceding claims wherein the formulation comprises 4, 7, 10, 13, 16, 19-docosahexaenoic acid (or "DHA").
7. A soft gelatin capsule as claimed in Claim 6 insofar as dependent from any of Claims 1 to 4 wherein DHA is present in an amount of between from about 20 wt % to about 30 wt % of the formulation.
8. A soft gelatin capsule as claimed in any of the preceding claims comprising between from about 100mg to about 2000mg of said formulation.
9. A soft gelatin capsule as claimed in any of the preceding claims comprising about 500mg of said formulation.

10. A soft gelatin capsule as claimed in any of Claims 1 to 8 comprising about 1000mg of said formulation.

11. A soft gelatin capsule as claimed in any of the preceding claims wherein the or
5 at least one omega-3 polyunsaturated fatty acid is in free acid form or in the form of a pharmacologically acceptable salt thereof.

12. A soft gelatin capsule as claimed in any of the preceding claims wherein the omega-3 polyunsaturated fatty acid is in free acid form.

10

13. A soft gelatin capsule as claimed in any of the preceding claims wherein the gelatin comprises porcine gelatin.

14. A soft gelatin capsule as claimed in any of Claims 1 to 12 wherein the gelatin
15 comprises bovine gelatin.

15. A soft gelatin capsule as claimed in any of Claims 1 to 12 wherein the gelatin comprises fish gelatin.

20 16. A soft gelatin capsule as claimed in any of the preceding claims wherein the wall of the capsule consists of a single layer.

17. A soft gelatin capsule as claimed in any of the preceding claims wherein the capsule delays release of the formulation until after passage through the stomach.

25

18. A soft gelatin capsule as claimed in any of the preceding claims wherein the capsule delays release of the formulation until after passage beyond the pancreatic duct in the duodenum.

30 19. A soft gelatin capsule as claimed in Claim 17 or Claim 18 wherein the capsule is coated with at least one enteric material.

20. A soft gelatin capsule as claimed in any of Claims 17 to 19 wherein at least one enteric material is integrated within the gelatin of the capsule.

21. A soft gelatin capsule as claimed in Claim 19 or Claim 20 wherein the or at least one enteric material is a neutral polyacrylate polymer.
- 5 22. A soft gelatin capsule as claimed in any of Claims 19 to 21 wherein the or at least one enteric material is poly(ethylacrylate-methylmethacrylate).
23. Use of gelatin extracted by an extraction process comprising acid pre-treatment of a collagen source in the manufacture of a medicament comprising at least
10 one soft gelatin capsule as defined in Claim 1 for the oral treatment or prophylaxis of a condition selected from chronic inflammatory conditions, hyperlipidaemia, hypertriglyceridaemia, asthma, bipolar disorder and neoplastic disease.
24. Use as claimed in Claim 23 wherein the medicament comprises at least one
15 soft gelatin capsule as defined in any of Claims 2 to 22.
25. A process for the manufacture of a soft gelatin capsule containing a pharmaceutical formulation comprising at least one omega-3 polyunsaturated fatty acid in free acid form or a pharmacologically acceptable derivative thereof, said
20 process comprising encapsulating said pharmaceutical formulation in gelatin extracted by an extraction process comprising acid pre-treatment of a collagen source.
26. Use of gelatin extracted by an extraction process comprising acid pre-treatment of a collagen source in a soft gelatin capsule containing a pharmaceutical
25 formulation comprising at least one omega-3 polyunsaturated fatty acid in free acid form or a pharmacologically acceptable derivative thereof to improve resistance of the soft gelatin capsule to chemical interaction with the formulation.
27. Use as claimed in Claim 26 wherein said resistance is greater than that of a
30 soft gelatin capsule containing a pharmaceutical formulation comprising at least one omega-3 polyunsaturated fatty acid in free acid form or a pharmacologically acceptable derivative thereof in which the gelatin consists essentially of gelatin extracted by an extraction process comprising alkali pre-treatment of a collagen source.

28. Use of gelatin extracted by an extraction process comprising acid pre-treatment of a collagen source in a soft gelatin capsule containing a pharmaceutical formulation comprising at least one omega-3 polyunsaturated fatty acid in free acid
5 form or a pharmacologically acceptable derivative thereof to improve shelf life of the soft gelatin capsule.

29. Use as claimed in Claim 28 wherein said shelf life is greater than that for a soft gelatin capsule containing a pharmaceutical formulation comprising at least one
10 omega-3 polyunsaturated fatty acid in free acid form or a pharmacologically acceptable derivative thereof in which the gelatin consists essentially of gelatin extracted by an extraction process comprising alkali pre-treatment of a collagen source.

15 30. A method of treatment or prophylaxis of a condition selected from chronic inflammatory conditions, hyperlipidaemia, hypertriglyceridaemia, asthma, bipolar disorder and neoplastic disease comprising administering a therapeutically effective amount of a pharmaceutical formulation comprising at least one omega-3 polyunsaturated fatty acid in free acid form or a pharmacologically acceptable salt
20 thereof per day in the form of a plurality of soft gelatin capsules as defined in Claim 1.

31. A method as claimed in Claim 30 wherein the soft gelatin capsules are as defined in any of Claims 2 to 22.

25 32. A soft gelatin capsule substantially as hereinbefore described with reference to the accompanying examples.

33. A process substantially as hereinbefore described with reference to the
30 accompanying examples.

34. A use substantially as hereinbefore described with reference to the accompanying examples.